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EXAMINER	
ROYDS, LESLIE A	

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1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,838	FIKSTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008 and 14 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,51,52,55,57-61,65,75,76,78 and 80-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,51-52,55,57-61,65,75-76,78 and 80-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *21 Aug 08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 35, 51-52, 55, 57-61, 65, 75-76, 78 and 80-82 are presented for examination.

Applicant's Amendment filed October 22, 2008 and Supplemental Amendment filed November 14, 2008 have each been received and entered into the present application.

Applicant's Information Disclosure Statement (IDS) filed August 21, 2008 (two pages total) has also been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08(A-B), the Examiner has considered the cited references.

Claims 35, 51-52, 55, 57-61, 65, 75-76, 78 and 80-82 remain pending and under examination. Claims 35, 59 and 60 are amended. Claims 54, 56, 77 and 79 are cancelled.

Applicant's arguments, filed October 22, 2008 and November 14, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 51-52, 55, 57-61, 65, 75-76, 78 and 80-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 35 reads upon a pharmaceutical composition comprising a therapeutically effective amount of cilostazol; a solubilizer selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, etc. (claim 35, l.3-12); and a release modulator which synchronizes the release of the drug, wherein the release modulator is selected from the group consisting of methylcellulose, a hydroxypropylmethylcellulose, etc. (claim 35, l.14-20), wherein the cilostazol is from 0.5-50% w/w of the composition, the solubilizer is present from 15-95% w/w of the composition, the release modulator is from 1-50% w/w of the composition, wherein the composition is formulated to release the cilostazol over an extended period of time, said extended period of time being between 2 and 24 hours, and wherein less than 50% of the cilostazol is released within the first two hours.

Present claim 59 is directed to substantially identical subject matter as present claim 35, but for the fact that it is specifically directed to an oral dosage form thereof.

Present claim 60 is also directed to substantially identical subject matter as present claim 35, but for the fact that it is specifically directed to a solid oral dosage form thereof.

In particular, the specification and claims as originally filed fail to provide adequate written description for the newly added limitation directed to "wherein less than 50% of the cilostazol is released within the first two hours" (claims 35 or 59-60).

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test

of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))…Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Applicant relies upon Figures 2 and 4 of the originally filed application, which each respectively correspond to the formulations of Examples 2 and 6. Example 2 is a formulation of cilostazol (125 mg), d-alpha-tocopherol polyethylene glycol succinate (572 mg), d-alpha tocopherol succinate (64 mg) and polyethylene glycol (52 mg). Figure 2, which corresponds to the release profile of the formulation of Example 2, demonstrates that slightly less than 40% of the cilostazol is released within the first two hours. Example 6 is directed to two formulations: (1) Formulation 6-1, which comprises cilostazol (25 mg), CREMOPHOR RH40 (125 mg), HPMC K4M (85 mg), talc (9 mg), colloidal SiO_2 (1 mg) and polyvinylpyrrolidone K90 (45 mg); and (2) Formulation 6-2, which comprises cilostazol (25 mg), CREMOPHOR RH40 (125 mg), HPMC K4M (85 mg), talc (9 mg), colloidal SiO_2 (1 mg), polyvinylpyrrolidone K90 (45 mg), and sodium dodecyl sulfate (2.5 mg). Figure 4, which corresponds to the release profile of the formulations of Example 6, demonstrates that slightly less than 25% of the cilostazol is released within the first two hours using Formulation 6-1 and slightly more than 25% of the cilostazol is released within the first two hours using Formulation 6-2. Note that, due to the limits of quantification on the y-axis of each of the proffered graphs, the *exact* percentage amount of cilostazol for each of the formulations of Example 2 and Example 6 cannot be determined.

While such formulations, testing and results have been fully and carefully considered, the compositions of Examples 2 and 6 are directed to very specific mixtures of cilostazol and release modulator/solubilizer combinations in particular amounts [i.e., Example 2 is 125 mg cilostazol, 572 mg d-alpha-tocopherol polyethylene glycol succinate, 64 mg d-alpha tocopherol succinate and 52 mg polyethylene glycol; Example 6-1 is 25 mg cilostazol, 125 mg CREMOPHOR RH40, 85 mg HPMC K4M, 9 mg talc, 1 mg colloidal SiO_2 and 45 mg polyvinylpyrrolidone K90; and Example 6-2 is 25 mg cilostazol, 125 mg CREMOPHOR RH40, 85 mg HPMC K4M, 9 mg talc, 1 mg colloidal SiO_2, 45 mg polyvinylpyrrolidone K90, and 2.5 mg sodium dodecyl sulfate], whereas the instant claims are significantly broader in scope regarding possible release modulator/solubilizers and combinations thereof, as well as ranges of amounts of each component. Such disclosure of these three specific cilostazol formulations fails to be supportive of the concept that less than 50% cilostazol is released within the first two hours from the composition using *any* claimed release modulator and/or *any* solubilizer component and/or *any* claimed %w/w of cilostazol, release modulator and/or solubilizer. The determination of less than 50% release of cilostazol within the first two hours (i.e., specifically, slightly less than 40% for the formulation of Example 2; slightly less than 25% for the first formulation 6-1 of Example 6; and slightly more than 25% for the second formulation 6-2 of Example 6) fails to provide adequate written support to now narrow the claims to read upon the same degree of cilostazol release when the composition does not comprise the same release modulators and/or the same solubilizers in the same amounts and proportions as those specifically used in, e.g., Examples 2 and 6. This newly added limitation represents a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and clearly is a concept that was not in Applicant's possession at the time of the invention.

Furthermore, this disclosure found in the specification and claims as originally filed also fails to support the concept of "less than 50%" cilostazol release. The compositions of Examples 2 and 6 each

release a very specific percentage amount of cilostazol within the first two hours: (1) for Example 2, the cilostazol release is slightly less than 40%, (2) for Example 6, Formulation 6-1, the cilostazol release is slightly less than 25%, and (3) for Example 6, Formulation 6-2, the cilostazol release is slightly more than 25%. Thus, the cilostazol release demonstrated with these three exemplary compositions does not cover the full range of 50% or less cilostazol release as now instantly claimed and, therefore, represents a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and clearly is a concept that was not in Applicant's possession at the time of the invention.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of "wherein less than 50% of the cilostazol is released within the first two hours" (claims 35 or 59-60).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35, 51-52, 55, 57-61, 65, 75-76, 78 and 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amselem et al. (U.S. Patent No. 5,891,469; 1999) in view of The Merck Index (Eleventh Edition, Monograph 2277; 1989, p.353-354), each already of record.

Amselem teaches pharmaceutical compositions capable of increasing the bioavailability of a lipophilic substance (col.5, l.40-50), comprising: (1) a lipophilic substance that possesses low water solubility and poor oral bioavailability (col.1, l.21-22), such as lipophilic substances that have a water solubility of less than 50 μg/ml (col.5, l.43-47), e.g., cannabinoids (col.5, l.44), which have aqueous solubility of a few micrograms or less, (2) the surfactant alpha-tocopherol polyethylene glycol succinate, usually with a mean molecular weight of 1000 (col.5, l.49-66), and further (3) at least one dispersion adjuvant, such as tocopherol acetate, polyvinylpyrrolidone, a medium or long chain triglyceride and/or polyethylene glycol (col.6, l.23-26 and col.6, l.58-66). Amselem also teaches that the disclosed composition may be administered in a therapeutically effective amount to a mammal in need of such a substance (see claim 19; col.14), wherein the substance may be in a gelatin capsule or tablet unit dosage form (see claims 9-10; col.14) and may also comprise any suitable nontoxic carrier or diluent powder or additive (col.7, 4-15). Amselem further teaches that the lipophilic substance is present from 0.01-50% of the total solid weight of the composition, the surfactant TPGS is present from 5-65% of the total solid weight of the composition and the dispersion adjuvant is present from 5-75% of the total solid weight of the composition (col.6, l.35-57).

The teaching of tocopherol polyethyleneglycol (PEG) succinate in Amselem, especially tocopherol polyethyleneglycol 1000 succinate, as the surfactant component of the disclosed pharmaceutical composition places the use of either the racemic or either enantiomeric form (d- or l-) of tocopherol PEG succinate clearly within the possession of the public. Furthermore, though Amselem et al. does not expressly recognize the "release modulating" properties of the, e.g., tocopherol PEG succinate, tocopherol acetate, polyvinylpyrrolidone, or medium or long chain triglyceride, the very teaching of the identical chemical entity in overlapping amounts clearly indicates that whatever release modulating properties that Applicant has attributed to either of these compounds are necessarily present, absent factual evidence to the contrary, since chemical compounds cannot have mutually exclusive properties. Please reference MPEP §2112.01.

Amselem fails to teach the use of cilostazol as the specific therapeutic drug of the instantly claimed pharmaceutical composition (claims 35 and 59-60); the synchronized release of cilostazol and solubilizer with a correlation coefficient of greater than 0.80 (claims 51 and 75) or the limitation "wherein the composition releases the cilostazol over 2-24 hours and wherein less than 50% of the cilostazol is released within the first two hours (claims 35 and 59-60).

In view of the fact that Amselem teaches the disclosed pharmaceutical compositions for formulating any of a variety of lipophilic substances, i.e., those with low water solubility and poor oral bioavailability, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to use such a delivery preparation for the formulation of other highly hydrophobic drugs (i.e., those with low water solubility and, thus, poor bioavailability), such as cilostazol, because, as The Merck Index teaches, this antithrombotic agent was well known in the art to be practically insoluble in water (see Monograph 2277). Accordingly, in view of the extensive hydrophobicity of the compounds taught by Amselem and cilostazol, the skilled artisan would have had a reasonable expectation of success in effectively solubilizing cilostazol in the delivery vehicle disclosed by Amselem because of the

demonstrated success in effectively solubilizing the exemplary hydrophobic agents (i.e., dexanabinol, CoQ10, etc.) of the reference into such a formulation. Further, such a person would have been motivated to do so in order to enable effective dosing of cilostazol with concomitant enhancement of resorption and bioavailability levels, reduced variability in resorption and bioavailability levels and also a concomitant reduction in the amount required to achieve effective dosing.

With regard to present claims 51 and 75, which are directed to the synchronized release of cilostazol and solubilizer with a correlation coefficient of greater than 0.80, such correlation values are, absent factual evidence to the contrary, present in the reference because Amselem teaches the formulation of the lipophilic drug with the surfactant and dispersion adjuvant compounds in clearly overlapping amounts and, thus, in the same ratios as presently claimed to produce a composition that is substantially the same as that presently claimed. In other words, the fact that Amselem teaches identical components in identical, or at the very least, overlapping, amounts is clearly indicative of the fact that any release characteristics attributed to such a composition would be necessarily present in the prior art of Amselem, absent factual evidence to the contrary. Please see MPEP §2112.01[R-3] ("Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705,709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)).

Similarly, with regard to present claims 35 and 59-60, which now specify that the composition is formulated to release the cilostazol between 2 and 24 hours and wherein less than 50% of the cilostazol is released within the first two hours, such properties are, absent factual evidence to the contrary, also present in the reference because Amselem teaches the formulation of the lipophilic drug with the

surfactant and dispersion adjuvant compounds in clearly overlapping amounts and, thus, in the same ratios as presently claimed to product a composition that is substantially the same as that presently claimed. In other words, the fact that Amselem teaches identical components in identical, or at the very least, overlapping, amounts is clearly indicative of the fact that such release characteristics would be necessarily present in the prior art of Amselem, absent factual evidence to the contrary. Again, please see MPEP §2112.01.

Note, further, that Applicant has argued that Amselem only teaches more than 50% release of the active agent over the first two hours following administration (p.9-13, Remarks filed November 14, 2008) and, therefore, cannot be applied as pertinent prior art over the instantly claimed invention. This is unpersuasive, since Amselem used very specific formulations of dexanabinol or coenzyme Q10, TPGS, and polyvinylpyrrolidone, also optionally with other dispersion adjuvants (see, e.g., Example 2) to measure the release of the active lipophilic ingredient over time as presented in the Figures of the reference. However, such formulations are exemplary embodiments of the disclosed invention of Amselem neither circumscribe the full scope of embodiments covered by the disclosure to Amselem nor limit the disclosure of Amselem to the activity and release shown with these exemplary compositions. In fact, Amselem encompasses a considerable scope of embodiments that comprise the same active agents in amounts that clearly fall within and/or overlap with the amounts of the instant claims wherein the release of the lipophilic ingredient was not specifically quantified and/or measured as was done with the exemplary formulations. However, in view of the fact that the pharmaceutical composition taught by Amselem comprises the identical active agents as presently claimed in overlapping amounts to those presently claimed, the composition of Amselem must necessarily possess the same release characteristics when administered as that presently claimed whether recognized by the patentee or not because products of identical chemical composition cannot exert mutually exclusive properties when prepared or used in the same manner under the same circumstances. In other words, if the prior art teaches the identical

chemical or physical structure of the composition (i.e., same active agents, same amounts, etc.), the properties that Applicant discloses and/or claims are necessarily present. Please reference MPEP §2112.

In re Best (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe includes functions and/or properties that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the newly cited function and/or property at the time of invention, so long as the function and/or property can be demonstrated to be reasonably expected to be present. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Note that, even though *Toro* was decided in the context of inherent anticipation, considerations of inherent teachings arise both in the context of anticipation and obviousness (see, e.g., *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) or *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983) and MPEP §2112).

Conclusion

Rejection of claims 35, 51-52, 55, 57-61, 65, 75-76, 78 and 80-82 is proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

February 12, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614